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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,860	07/12/2004	Jeffrey Owen Phillips	04242373	1266

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/795,860	PHILLIPS, JEFFREY OWEN	
	Examiner	Art Unit	
	FRANK CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *75,77,84-89 and 91* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *75,77,84-89 and 91* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *21 october 2008* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 75, 77, 84-89, 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCullough (US Pat. 5,447,918) in view of Carroll, EP 584,588, Whittle et al. (US Pat. 6,268,385) and the applicant's admission.

The claimed invention is directed to a tablet containing about 10 to about 40 mg of a non-enteric coated omeprazole or salt thereof, a buffering agent comprising about 1 mEq To about 20 mEq sodium bicarbonate and a disintegrant.

McCullough disclose a tablet containing 20-300 mg omeprazole, 400-500 mg calcium carbonate and carboxymethyl cellulose (Columns 15, 16, example 12). The use of one or more of aluminum hydroxide, magnesium hydroxide, potassium or sodium bicarbonate, calcium carbonate, magnesium carbonate is also disclosed (Column 8, lines 15-35).

Carroll et al. disclose the use of sodium bicarbonate to stabilize omeprazole in the gastric environment (Abstract).

EP 584,588 discloses a non-enteric coated anti-ulcer PPI and a basic material, such as alumina magnesium hydroxide, aluminum hydroxide, magnesium hydroxide, sodium carbonate, calcium carbonate, magnesium carbonate, sodium hydrogen carbonate, potassium hydrogen carbonate, magnesium hydrogen carbonate, calcium hydrogen carbonate, and that the amount of

basic material may be present in an amount of 50 to 2000 weights per 100 weight parts (Pages 3-6). It is disclosed that the basic material is used to preserve the stability of the acid-labile imidazole derivative in the stomach (Page 6, lines 19-21). It is disclosed that omeprazole and imidazole derivative are both acid-labile (Example 1 at pages 6,7). It is disclosed that the composition can be administered orally, in the form of tablets, pellets, capsules, powder, granules, syrup, paste and the like and that they can contain excipients, disintegrants, binders, lubricants, pigments, diluents and the like which are commonly employed in the art (Page, 6, lines 28-35).

Whittle et al. discloses that esomeprazole is S-omeprazole (Column 19, lines 51-54). Methods of preparing oral dosage forms including mixing the active ingredient with an alkali material which creates a micro-pH of not less than pH of 7, preferably not less than a pH of 8 chosen from such materials as sodium, potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, or other suitable weak inorganic or organic acids; substances typically used in antacid preparations such as aluminum, calcium, and magnesium hydroxides; magnesium oxide or composite substances such as, for example, Al.sub.2 O.sub.3.6MgO CO.sub.2.12H.sub.2 O (Mg.sub.6 Al.sub.2.(OH).sub.16 CO.sub.3 4H.sub.2 O), MgO.Al.sub.2 O.sub.3, 2SiO.sub.2.nH.sub.2 O, wherein n is not necessarily a whole number and may be less than 2, or similar compounds (Column 43, lines 6-34). It is disclosed that the above mixture may then be formulated into pellets or tablets or gelatin capsules which may then be used as cores for further processing, for example, enteric coating (column 43, column 44). It is disclosed that the tablets can contain lubricating agents, fillers and bulking agents and disintegrating agents (Columns 41, 42). It is disclosed that the preferred dosages of the active

ingredients is from about 8 mg to about 10 mg, about 16 mg to about 20 mg, and about 32 mg to about 40 mg, especially 10 mg, 20 mg and 40 mg per dosage unit (Column 41, lines 9-20). An example is disclosed containing croscarmellose sodium (Column 66, lines 15-30).

The Applicant admits that omeprazole is a H+, K+-ATPase proton pump inhibitor and is available in micronized form (Specification, Page 12, lines 18-31, Page 17, line 18)

McCullough disclose a tablet containing 20-300 mg omeprazole and 400-500 mg calcium carbonate and that aluminum hydroxide, magnesium hydroxide, potassium or sodium bicarbonate, calcium carbonate, magnesium carbonate can also be used. The difference between the McCullough and the claimed invention is that McCullough does not expressly disclose the use of disintegrants, such as croscarmellose sodium, and micronized omeprazole. However, the prior art amply suggests the same as the Carroll et al. disclose the use of sodium bicarbonate to stabilize omeprazole in the gastric environment; EP 584,588 discloses a non-enteric coated PPI containing basic material and that omeprazole is acid sensitive and the use of basic material to active agent of 2000:100 ; Whittle et al. disclose the use of buffering agents such as sodium bicarbonate and magnesium hydroxide and tablets containing excipients such as disintegrants (including croscarmellose sodium); and the Applicant admits that omeprazole is a PPI and is available in micronized form. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the combination of the non-enteric coated PPI with the basic substance, such as sodium bicarbonate and magnesium hydroxide, including at a ratio of 2000:100 (buffer:PPI) would protect the PPI from stomach acid, that the product can be effectively administered as a

tablet, that croscarmellose sodium would be a suitable disintegrant and that micronized omeprazole would be a suitable form of omeprazole.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As such, there is no requirement that McCullough disclose the claimed range of omeprazole in conjunction with the claimed range of sodium bicarbonate, that Caroll disclose a tablet, that EP 584,588 disclose the combination of omeprazole and buffer in a tablet. Further, contrary to the Applicant's arguments, none of the claims exclude the use of sucralfate. As such, the claimed invention does not teach away from the use of sucralfate.

There is no requirement that the art provide an express disclosure to combine a non-enteric coated omeprazole with sodium bicarbonate and a disintegrant in a tablet. The prior art as indicated above does disclose a tablet containing omeprazole and sodium bicarbonate. McCullough does not disclose that the omeprazole is enteric coated. As such, McCullough discloses a tableted omeprazole that is not enteric coated. Further, Whittle does not require that the tablet be enteric coated. As such, Whittle, contrary to the Applicants arguments, discloses a non-enteric coated tablet which can contain omeprazole, a buffering agent and a disintegrant, i.e. croscarmellose sodium, as indicted above. Further, EP 584,588 suggests that the buffering agent, sodium bicarbonate would be effective in stabilizing acid labile compounds. As such, one of

ordinary skill in the art would expect that sodium bicarbonate would be able to stabilize omeprazole which is disclosed to be acid labile.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references and the Applicant's admission.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 75, 77, 84-89, 91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,780,882, claims 1, 2, 9-13, 15, 17, 24-41, 49, 50, 52, 53, 57-72, 80-88, 95-102, 110, 111, 113-118 of U.S Pat. No. 6,489,346, claims 1-3, 10-29 of U.S. Pat. No. 6,645,988 and claims 1-3, 5-24, 25, 29-47, 50 of US Pat. 6,699,885. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass tablets containing the combination non-enteric coated benzimidazole PPI, such as omeprazole, including micronized omeprazole, sodium bicarbonate and other buffers, including magnesium hydroxide, and excipients, such as a disintegrant, such as croscarmellose sodium which is defined by the Specification to include croscarmellose sodium (US Pat. '882, Column 17, lines 25-30; US Pat. '885, Column 22, lines 20-23; US Pat. '988, Column 13, line 43-45). See *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Co.*, 95 USPQ2d 1797 (Fed. Cir. 2010) (the specification's disclosure may be used to determine whether a claim "merely define[s] an obvious variation of what is earlier disclosed and claimed," "to learn the meaning of [claim] terms," and to "interpret the coverage of [a] claim.").

The Applicant does not traverse the double patenting rejection, as such, the rejection is maintained.

Claim 75, 77, 84-86, 88, 89, 91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9, 11, 13, 16-21 of US Pat. 7,399,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass tablets containing the combination non-enteric coated benzimidazole PPI, such as omeprazole, including micronized omeprazole, sodium bicarbonate and other buffers, such as magnesium silicate, calcium hydroxide, calcium acetate or calcium lactate, and excipients, such as a disintegrant, such as croscarmellose sodium.

The Applicant does not traverse the double patenting rejection, as such, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
November 7, 2011

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616